

Robert Shull, M.D.

Page 1

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON

Master File No. 2:12-MD-02327  
MDL 2327

JOSEPH R. GOODWIN  
U.S. DISTRICT JUDGE

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IN RE: ETHICON, INC. PELVIC §  
REPAIR SYSTEM PRODUCTS §  
LIABILITY LITIGATION §

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Ana Ruebel v. Ethicon, Inc. et al. §  
Civil Case No. 2:12cv00663 §

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Harriet Beach v. Ethicon, Inc. et al. §  
Civil Case No. 2:12cv00476 §

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Carol Jean Dimock v. Ethicon, Inc. et al. §  
Civil Case No. 2:12cv00401 §

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- - -  
MARCH 10, 2016  
- - -

Video deposition of Robert Shull, M.D.,  
held at Beck Redden, LLP, 515 Congress,  
Suite 1900, Austin, Texas 78701, commencing  
at 9:54 a.m., digitally recorded at the date  
and time aforesaid and transcribed by  
Danielle Coleman, Court Reporter.

- - -  
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Robert Shull, M.D.

Page 2

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11 Also present:

12 PETER ZIERLIEN, VIDEOGRAPHER

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Robert Shull, M.D.

Page 3

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Testimony of: ROBERT SHULL, M.D.

PAGE

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DIRECT EXAMINATION BY MS. VAN STEENBURGH.....

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5

E X H I B I T S

6

DEPOSITION

PAGE

7

EXHIBIT NO. 1

NOTICE OF TAKING DEPOSITION

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(Retained by Ms. Van Steenburgh)

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Robert Shull, M.D.

Page 4

1 THE VIDEOGRAPHER: We are now on the record.  
2 My name is Peter Zierlien. I'm a videographer for  
3 Golkow Technologies. Today's date is March 10th,  
4 2016. The time is 9:54 a.m. This video deposition  
5 is being held in Austin, Texas, in the matter of  
6 Carol Jean Dimock versus Ethicon, Inc., for the  
7 United states District Court, Southern District of  
8 West Virginia at Charleston. The deponent is  
9 Dr. Robert Shull.

10 Will counsel please identify yourselves for  
11 the record?

12 MR. CANNON: Doug Cannon appearing on behalf  
13 of the plaintiff.

14 MS. VAN STEENBURGH: Tracy Van Steenburgh on  
15 behalf of the defendants.

16 THE VIDEOGRAPHER: Will you raise your right  
17 hand, sir? Do you swear or affirm that the  
18 testimony you give here today will be the truth,  
19 the whole truth, and nothing but the truth?

20 THE WITNESS: I do.

21 ROBERT SHULL, called as a witness by the  
22 Defendants, having been first duly sworn, testified as  
23 follows:  
24

Robert Shull, M.D.

Page 5

1 DIRECT EXAMINATION

2 BY MS. VAN STEENBURGH:

3 Q. Good morning, Dr. Shull.

4 A. Good morning.

5 Q. We met off the record, but I'll introduce  
6 myself again. I'm Tracy Van Steenburgh and I represent  
7 the defendants in a lawsuit brought by Carol Jean  
8 Dimock, and we are here today to ask you some questions  
9 about your expert opinion relative to Ms. Dimock's case.  
10 You've had your deposition taken before, I take it?

11 A. Yes, I have.

12 Q. I will not go through all of the rigmarole in  
13 terms of what we're going to be doing and the logistics  
14 of it, then. The only thing that I do like to say is I  
15 fancy myself as being somewhat articulate, but if I am  
16 not and you don't understand a question that I've asked,  
17 please ask me to rephrase it, ask it in a different  
18 way; otherwise, I'll just assume you understood the  
19 question when you answer it. Fair enough?

20 A. Yes.

21 (Exhibit No. 1 was marked for identification.)

22 Q. All right. Doctor, I'm showing you what's  
23 been marked as Deposition Exhibit 1. I'll represent to  
24 you that that is a notice of taking deposition in

Robert Shull, M.D.

Page 6

1 connection with the Dimock case along with a couple of  
2 other cases you're going to sit for today, and as part  
3 of the notice of taking deposition, you were asked to  
4 some bring some materials with me -- with you. Did you  
5 bring some today?

6 A. Yes, I did.

7 Q. Okay. And what did you bring with you as  
8 materials?

9 A. I have a current copy of my curriculum vitae.

10 Q. Okay.

11 A. I have the notice that you have referred to  
12 previously.

13 Q. Thank you.

14 A. I have the schedule of time I've spent in  
15 preparation and the billing for the preparation. I  
16 have the records, which are adjacent in a file box  
17 which you can see at the end of the table. I have  
18 the case-specific opinion from Dr. Shoemaker and the  
19 medical evaluation when Dr. Shoemaker examined  
20 Mrs. Dimock, and I have a chronology of records  
21 relating to her care, which was provided to me by  
22 Mr. Cannon's law firm to summarize the chronology of  
23 events. I have a copy of the office visit Ms. Dimock  
24 made when she saw me on the 25th of November, 2015.

Robert Shull, M.D.

Page 7

1           Q.    With respect to the medical records that you  
2           brought with you today, I noticed that some of them were  
3           tabbed. Was there a rhyme or reason for the tabs that  
4           you attached to the medical --

5           A.    Only because the volume of records was so  
6           great that it is impossible to get back to something  
7           meaningful without having some type of a marker.

8           Q.    With respect to the chronology that was  
9           provided to you by Mr. Cannon's office, if you wouldn't  
10          mind letting me take a look at that real quick.

11          A.    (Witness complies.)

12          Q.    Thank you. And it looks like this is a  
13          chronology that has a date, the name of the provider,  
14          the occurrence or treatment, and then a reference to  
15          certain Bates numbers. This was prepared by counsel and  
16          provided to you; is that right?

17          A.    Yes.

18          Q.    All right. And the -- some of the entries are  
19          highlighted in yellow. Was that done before you got the  
20          chronology?

21          A.    You know, it's possible some of them were.  
22          They are also notes of mine in when I was reading them,  
23          so I highlighted some things and have some handwritten  
24          notes in the margins.

Robert Shull, M.D.

Page 8

1 Q. And that's what I was going to ask, there was  
2 some handwritten notes here, and I take it those are  
3 your handwritten notes, correct?

4 A. Yes.

5 Q. All right. And then with respect to you had  
6 mentioned that you had made some notes at or about the  
7 time that you visited with and examined Ms. Dimock, and  
8 that is contained in a transcribed set of progress  
9 notes; is that right?

10 A. It is, and that has my own markings, because I  
11 highlighted and excerpted from that for the final  
12 report. I didn't include everything that I had dictated  
13 and I wanted to highlight the areas I wanted to include.

14 Q. Okay. And just so I am clear, you examined  
15 Ms. Dimock in Texas?

16 A. Yes.

17 Q. All right.

18 A. She came to my office in November of 2015.

19 Q. And your -- and you followed your normal  
20 procedure, which was to conduct an examination and do a  
21 dictation of your -- the history and the findings at or  
22 about that same time?

23 A. On the same day.

24 Q. On the same day. Okay. And then those are



Robert Shull, M.D.

Page 9

1 transcribed by somebody else and put into a final  
2 report?

3 A. Yes. They are dictated and another person  
4 transcribes them and then I validate them.

5 Q. Okay. In addition to the chronology and your  
6 notes, I also note there are some documents in the  
7 notebook that look like there maybe is an operative  
8 report, and that contains some of the notes that you --

9 A. Yes.

10 Q. -- had as well?

11 A. Yes.

12 Q. Is that right?

13 A. Yes.

14 Q. And that appears to be the operative report  
15 from the date of implant by Dr. Housel; is that right?

16 A. I think there are several operative reports --

17 Q. Okay.

18 A. -- because she's had several procedures.

19 Q. All right. And you prepared an expert report  
20 in connection with Ms. Dimock's case, correct?

21 A. Yes, I did.

22 Q. All right. And what is the date of that  
23 report, if you don't mind, if you know?

24 A. It would be -- I don't know the exact date.

Robert Shull, M.D.

Page 10

1 It would be the last week of January of 2016, and it's  
2 possible that I -- that Mr. Cannon's office has the  
3 date which it was received. It was prior to February  
4 the 1st, and it would have been one of those last few  
5 days of January, 25th or 6th possibly. I don't remember  
6 that for certain.

7 Q. And I don't know if this may help you, you  
8 gave me a copy of your billing statement, and it looks  
9 like you had prepared a draft and that you may have had  
10 a final call with Mr. Cannon on or about the 26th of  
11 January?

12 A. That's correct.

13 Q. So using that as the date, when were you first  
14 asked to get involved in connection with the claims by  
15 Ms. Dimock?

16 A. I believe the first correspondence I had with  
17 Mr. Cannon's office was in the fall of 2015. I don't  
18 remember the exact month. I don't have that letter with  
19 me.

20 Q. Okay. And that was a direct contact from  
21 Mr. Cannon's office to you, or is it through somebody  
22 else?

23 A. It was through his paralegal originally.

24 Q. Okay.

Robert Shull, M.D.

Page 11

1           A.    And then he and I corresponded. I emailed him  
2           and/or called him to get information to decide if this  
3           was something that fell into an area I had an interest  
4           in and knowledge enough to be of assistance.

5           Q.    And what kinds of -- I mean, did you ask him  
6           for materials in order to review it to assess that?

7           A.    No. I asked him mainly about the patient  
8           herself, what the possible concerns are, and what were  
9           his expectations. Did he simply want me to review the  
10          record and contact him? Did he want me to write a  
11          case-specific report, simply to see her in consultation?  
12          I wasn't clear in the beginning what he was asking me to  
13          do.

14          Q.    Okay. And I noticed in some of the materials  
15          that you brought with you there are some handwritten  
16          notes. I'll strike that. It looks like these are from  
17          something else.

18                What was it that Mr. Cannon asked you to do in  
19          connection with the Dimock case?

20          A.    Eventually, what he asked me to do, would I  
21          see her for a medical evaluation, would I evaluate her  
22          prior records, her current exam, and be willing to write  
23          a case-specific report about her, I guess, fact sheet  
24          would be the right word. I'm not sure I saw it at the

Robert Shull, M.D.

Page 12

1 time, what was contained in the fact sheet about her  
2 injuries associated with the product that had been  
3 implanted in her.

4 Q. And prior to that, you and Mr. Cannon had  
5 talked about her case, and that was so that you could  
6 assess whether this was something within your area of  
7 expertise?

8 A. Yes. And to find out what he actually  
9 expected someone to do, because I -- did it fit in a  
10 calendar that I could do it? Was it something I was  
11 knowledgeable about?

12 Q. And what was the nature of the scope of the  
13 engagement, besides seeing her for evaluation,  
14 evaluating her records; more specifically, were you  
15 asked to provide some kind of opinion as to whether  
16 there was a cause-and-effect relationship between the  
17 implant and her injuries?

18 A. Yes.

19 Q. Okay. Now, were you asked as part of the  
20 scope of your engagement to determine whether -- well,  
21 let me strike that.

22 In your review, Ms. Dimock received a Prolift  
23 device as part of her procedure that Dr. Housel  
24 performed back in 2008, correct?

Robert Shull, M.D.

Page 13

1 A. That's accurate.

2 Q. And Dr. Housel also implanted something called  
3 a TVTO vaginal sling, correct?

4 A. Yes.

5 Q. All right. Were you asked to provide an  
6 opinion as to whether the Prolift device caused the  
7 injuries that Ms. Dimock claims she now suffers?

8 A. I was.

9 Q. Okay. Were you asked to provide an opinion as  
10 to whether the TVTO device caused any of the injuries  
11 that Ms. Dimock claims she has suffered?

12 A. He asked if I was interested in that. I told  
13 him I was not likely to be prepared to do that on the  
14 TVT.

15 Q. All right. And why is that?

16 A. Because, one, we have a long record of  
17 knowledge about TVT. We are reasonably familiar with  
18 its success, with the side effects, and potential  
19 complications. It's accepted as a method of treatment  
20 for urinary incontinence. I, in fact -- I don't use a  
21 TVTO. I do use a retropubic TVT, so I feel as if I'm  
22 knowledgeable about that.

23 Prolift has a much shorter history with less  
24 objective information about its indications,

Robert Shull, M.D.

Page 14

1 complications, and potential problems, and the truth is  
2 that some of her physical findings could only be related  
3 to the Prolift because of the areas in the vaginal canal  
4 where the exposure is identified.

5 Q. So just so that we are clear, you are not here  
6 today and have not prepared any report or are prepared  
7 to give an opinion as to whether the TVTO in any way  
8 caused any injury to Ms. Dimock; is that right?

9 A. That's accurate.

10 Q. Okay. Did you look at the records relative to  
11 the implantation of the TVTO and her subsequent medical  
12 treatment?

13 A. Yes, I did.

14 Q. Okay. And do you believe that the TVTO was  
15 effective for her stress urinary incontinence?

16 A. To the best of my knowledge, it was helpful  
17 for her stress urinary incontinence. She still had  
18 urinary complaints. Probably not stress incontinence  
19 but symptoms compatible with urgency incontinence or  
20 overactive bladder.

21 Q. Okay. And urinary incontinence and overactive  
22 bladder are usually not treated with a device such as a  
23 TVTO; is that correct?

24 A. That wouldn't be a standard method of therapy

Robert Shull, M.D.

Page 15

1 for those complaints.

2 Q. Okay. And are you here today to provide any  
3 opinions relative to any urinary incontinence issues  
4 that Ms. Dimock might be currently experiencing?

5 A. Well, if you ask me questions about her  
6 symptoms, if I can answer them appropriately, I will.

7 Q. Okay. And the question, I guess, more  
8 specifically is have you been asked to provide any  
9 opinions relative to whether Prolift has caused any of  
10 the issues that Ms. Dimock currently experiences with  
11 urinary incontinence?

12 A. Not with her current complaints. When I  
13 looked at the records, there were some concerns possibly  
14 related to urethral obstruction associated with the  
15 Prolift and Dr. Norton's preoperative and intraoperative  
16 notes indicate some of that, so I feel comfortable  
17 answering questions about that if you ask about them.

18 Q. Okay. And with respect to Dr. Norton's  
19 findings in her notes, there was never any finding of  
20 any kind of urethral obstruction with Ms. Dimock; is  
21 that right?

22 A. There was no objective evidence that she could  
23 not empty her bladder effectively, for example.

24 Q. Okay. There are references in her record to

Robert Shull, M.D.

Page 16

1       some experience with urinary retention. Do you remember  
2       seeing that?

3           A.    Yes. What I don't remember, and maybe you  
4       have that, but I don't remember seeing it, the  
5       documentation of a continued what are called postvoid  
6       residual volumes, elevated postvoid residual volumes.  
7       There may be something. I don't recall that off the top  
8       of my head.

9           Q.    Okay. Well, the reason I ask is there are  
10      some references in there to some of the medications that  
11      she was taking that one of the side effects is urinary  
12      retention. I don't recall if you saw that or not?

13          A.    Yes.

14          Q.    Okay.

15          A.    She was taking some antispasmodics, and some  
16      antispasmodics relax the bladder, and one of the  
17      potential side effects is it may either take longer to  
18      void or you may have incomplete voiding.

19          Q.    Okay. Doctor, your report that you prepared  
20      in connection with Ms. Dimock's case is based in part on  
21      your review of her medical records, correct?

22          A.    Yes.

23          Q.    And is it also based in part on your medical  
24      examination of Ms. Dimock?



Robert Shull, M.D.

Page 17

1 A. Yes.

2 Q. And then it's also based in part on your  
3 clinical experience?

4 A. Yes.

5 Q. And also your review of the literature?

6 A. Yes.

7 Q. Okay. Did you review Ms. Dimock's medical  
8 records prior to performing a medical examination of  
9 Ms. Dimock?

10 A. I had access to some of her records that had  
11 been given to me in advance, not the entire record, and  
12 even if I had received all of those records, it would  
13 have been impossible to review them before I saw her.  
14 And then I spoke to her directly before examining her  
15 about her own knowledge of the history of her  
16 obstetrical history, surgical history, and her current  
17 complaints.

18 Q. And I guess more specifically, when you said  
19 you had received some records, do you recall, did you in  
20 fact review some of her medical records prior to meeting  
21 with her?

22 A. I cannot tell you for certain which ones, but  
23 I believe that I had access to her operative note from  
24 2008 and to at least some, if not all, of her explant

Robert Shull, M.D.

Page 18

1 procedures following that.

2 Q. Okay. And those would have been procedures  
3 primarily performed by Dr. Norton?

4 A. Yes.

5 Q. Okay.

6 A. Normally, I would like to have those when  
7 someone is being seen for evaluation after having had  
8 prior surgery. It's helpful to see the operative notes  
9 because in general they are more informative than the  
10 history is.

11 Q. With respect to the medical records, how did  
12 you decide which medical records to reference in your  
13 report?

14 A. What I wanted to do was understand something  
15 about her history before she had surgical management in  
16 Utah. So there were some things in her record that I  
17 could see, but that came in part from simply  
18 interviewing her about her past surgical history when  
19 she was living in California. And then in the remainder  
20 of the records what happened now is when you, for  
21 example, request a record or someone sends me a record,  
22 it would be an exhaustive copying of every conceivable  
23 thing, including in-hospital stays, a lot of nursing  
24 documentation, which is appropriate for nurses to know

Robert Shull, M.D.

Page 19

1       about. It isn't necessarily something that would be  
2       helpful in understanding the details of how the patient  
3       feels or about the surgical procedure. So what I've  
4       tried to do is find the parts of the record that  
5       actually involve a face-to-face encounter with one of  
6       the health-care providers, either in the outpatient  
7       clinic or in the operating room or the recovery period,  
8       as opposed to documentation for all of the other things.

9           Also with electronic medical records, many things  
10       are repeated over and over and over again. I'm sure  
11       you've seen that, so once you've read that particular  
12       entry one time, it normally isn't necessary to read it  
13       on every other time that it's repeated in the medical  
14       record.

15           Q.    Now, your report includes a summary of certain  
16       medical records and also includes a -- your summary of  
17       your examination of Ms. Dimock, correct?

18           A.    That's accurate.

19           Q.    All right. So let's talk a little bit about  
20       the format. I'd like to talk about the examination and  
21       when she came down to meet with you.

22           A.    Yes.

23           Q.    That was in November of 2015, correct?

24           A.    November the 25th, 2015.

Robert Shull, M.D.

Page 20

1 Q. Okay. And where did the examination take  
2 place?

3 A. In my office in Temple, Texas.

4 Q. Okay. And was anyone else present?

5 A. No, not with her. She came by herself, and I  
6 inquired when she came if I were free to share her  
7 information with Mr. Cannon, and she gave me permission  
8 to do that. He wasn't there, but she was comfortable  
9 letting me either copy him the records or -- I can't  
10 remember if I spoke to him, quite honestly, but he had  
11 access to the information in the record.

12 Q. Prior to the examination, did you talk with  
13 any of Ms. Dimock's physicians?

14 A. No. And I haven't since.

15 Q. Okay.

16 A. I haven't spoken to anyone else about it.

17 Q. And the same question as to any of her family  
18 members?

19 A. I haven't met anyone. I think she is single  
20 and she has one child whom I've never met and never  
21 spoken to.

22 Q. All right. How long did the examination take?

23 A. Her visit, I would say it was probably 45  
24 minutes to an hour from the time I saw her, interviewed

Robert Shull, M.D.

Page 21

1 her, examined her, then she would get dressed and come  
2 back to my office, and we sat down to discuss her  
3 history, the physical exam, answer her questions, and I  
4 tried to give her as much information as I had about  
5 what I thought I saw and felt and what some options for  
6 her would be regarding management of her pain complaints  
7 primarily.

8 Q. And the recommendations or what you thought  
9 about how to manage her pain complaints, are those  
10 contained in your report?

11 A. Yes, they are. And they're --

12 Q. Was there anything else you shared with her  
13 that is not in your report with respect to  
14 recommendations on treatment?

15 A. No. And my expert report has a condensed  
16 version of my entire outpatient recording, but the  
17 entire outpatient encounter is in the records that I  
18 have here.

19 Q. And just so that I am clear, the examination  
20 you said was 45 minutes to an hour, and then after-  
21 wards she came to your office and spent more time --

22 A. That was --

23 Q. -- or the whole --

24 A. -- the entire visit.

Robert Shull, M.D.

Page 22

1 Q. The entire visit --

2 A. Yes.

3 Q. -- was between 45 minutes and an hour?

4 A. Right.

5 Q. Okay. And with respect to the history that  
6 you took from Ms. Dimock, did that occur at the  
7 beginning, before the physical examination, or  
8 afterwards?

9 A. It's before.

10 Q. Okay.

11 A. So normally, what I would do is introduce  
12 myself to someone, particularly someone I've never met  
13 previously, discuss the history in as much detail as  
14 possible. Then after I've obtained the history, then  
15 the patients prepare for -- I leave the room. The  
16 patients prepare for an exam. I come back and examine  
17 her. After the exam, she then gets dressed and after  
18 she's dressed and comfortable, then she would come to  
19 the office and we would discuss it.

20 Q. Very good. Thank you. And just so I'm clear  
21 on logistics. During the time that you are taking the  
22 history and doing the examination, are you  
23 contemporaneously dictating?

24 A. No.

Robert Shull, M.D.

Page 23

1 Q. Okay.

2 A. What happens now with electronic medical  
3 records, you can enter all of those things while you're  
4 interviewing the patient. I don't do that. I interview  
5 them, discuss everything with them, and when they leave,  
6 then I document the electronic records and dictate the  
7 encounter.

8 Q. If -- do you have a copy of your report?

9 A. Yes. Of the expert report?

10 Q. Yes.

11 A. Yes, I do.

12 Q. There is a section in the ex report that  
13 starts at Page 8 where it indicates you personally  
14 interviewed and examined Ms. Dimock on November 25,  
15 2015. If you would turn to that.

16 A. I see it.

17 Q. Okay. I want to make sure that I understand  
18 the format. It looks as though you took the history and  
19 have recorded the history that goes through Page 10 to  
20 the bottom, where then you describe the examination; am  
21 I correct on that?

22 A. It looks as if that's the case.

23 Q. Okay. Did you prepare this report yourself?

24 A. Yes.

Robert Shull, M.D.

Page 24

1 Q. And then on Page 11, there is a section that  
2 starts in the middle of the page saying "Diagnosis"?

3 A. Yes.

4 Q. And that would be a diagnosis that you -- was  
5 based on your taking the history and your examination  
6 and evaluation; is that right?

7 A. Yes. That's still a continuation of her  
8 personal visit with me on the 25th of November.

9 Q. Okay. And then on Page 12, starting at the  
10 top, it looks to be the area where you start providing  
11 information regarding your differential diagnosis and  
12 your opinions relative to Ms. Dimock's injuries; is that  
13 right?

14 A. Yes.

15 Q. All right. I'd like to ask you a few  
16 questions relative to the history, so that I understand  
17 what you were asking and what Ms. Dimock was telling  
18 you, and this is kind of a question-and-answer kind of  
19 format; is that right?

20 A. Sure.

21 Q. I mean, not here, but when you were talking to  
22 Ms. Dimock?

23 A. Yes.

24 Q. Yes. All right.



Robert Shull, M.D.

Page 25

1 A. That's correct.

2 Q. And were you restricted in any way from asking  
3 her any questions that --

4 A. Not to the best of my knowledge.

5 Q. Okay. So on Page 8, it refers to the fact  
6 that she had a hysterectomy and an oophorectomy in the  
7 mid-'90s. Do you recall whether that was a total  
8 hysterectomy or a laparoscopic hysterectomy?

9 A. I don't know the answer to that.

10 Q. Okay. Would that make a difference to you in  
11 terms of any of your opinions in the case?

12 A. No.

13 Q. Okay. Now, it also looks on Page 9 that she  
14 said she'd never had any symptoms of fibromyalgia,  
15 correct?

16 A. That's accurate.

17 Q. And was it that -- she reported she'd had no  
18 history of chronic pain prior to having the mesh  
19 surgery; is that right?

20 A. That's accurate.

21 Q. Okay. So how do you define chronic pain --

22 A. I would --

23 Q. -- as you have written it here?

24 A. In the history?

Robert Shull, M.D.

Page 26

1 Q. Right.

2 A. Well, I would ask a patient very specifically,  
3 "Do you have a history of fibromyalgia, yes or no? Do  
4 you have a history of migraine headaches, chronic joint  
5 disease, rheumatoid arthritis, lupus, anything that  
6 could be associated with chronic pain?"

7 Q. Okay.

8 A. And her response to that was she had no  
9 history of any of those things prior to her surgery,  
10 and, in fact, I'm not sure she even has a current  
11 history of any of them, to be quite honest.

12 Q. Okay. In taking her history, did you talk  
13 with her about any history of previous pelvic pain that  
14 she had experienced?

15 A. In the past, I talked to her about  
16 hysterectomy. It's not uncommon when a woman has a  
17 hysterectomy that among whatever the reasons are, pelvic  
18 pain may be one of the reasons, it may be associated  
19 with menstruation, with ovulation, with poor support.  
20 So it's reasonably common in a woman who has had a  
21 hysterectomy that one of the complaints would have  
22 been painful menstruation or painful ovulation.

23 Q. Did Ms. Dimock tell you that she had been  
24 treated for pelvic pain syndrome in the past?

Robert Shull, M.D.

Page 27

1           A.    I'm not aware that she had chronic treatment  
2           for that. She may have had -- sometimes when she  
3           developed abdominal or pelvic pain, it was seen  
4           intermittently, but I'm not aware that was a chronic  
5           issue with her.

6           Q.    Okay. And just so you and I are on the same  
7           page, when you say not a chronic issue, how would you  
8           define that, that it's an ongoing -- well, you define it  
9           for me?

10          A.    Well, it'd be -- usually chronic means lasting  
11          six months or longer, or is recurrent, maybe  
12          intermittent over a period of years with the same signs  
13          and symptoms.

14          Q.    So to the best of her recollection in response  
15          to your -- well, strike that.

16                Based upon the history that she provided to  
17          you, you did not understand that she had had chronic  
18          pelvic pain in the past, prior to the mesh surgery; is  
19          that right?

20          A.    That's correct.

21          Q.    Okay. In the history, it looks like she told  
22          you that prior to her surgery in 2008, she had engaged  
23          in a relationship where she had had sex on a regular  
24          basis, is that right, and never had -- sorry -- and not

Robert Shull, M.D.

Page 28

1 had complaints associated with sexual intercourse; is  
2 that right?

3 A. Not -- that's accurate.

4 Q. Okay. And she told you that for about a year  
5 prior to the surgery, which was in 2008, she had not had  
6 any sexual intercourse; is that correct?

7 A. Yes.

8 Q. Is it your understanding based on talking with  
9 her that from the mesh surgery to the time that you  
10 examined her, she had not engaged in sexual intercourse?

11 A. That's correct.

12 Q. Now, in the history, it says approximately  
13 three to six months before seeing Dr. Norton in 2010 she  
14 developed complaints with what she calls pulling,  
15 ripping, and a sense of stabbing pain in the pelvis.  
16 There's a reference to her working with a bicycle pump?

17 A. I presume what she was doing is blowing up a  
18 tire or bicycle tire or a ball or something that  
19 required you -- if she had used one the way you or I  
20 probably would, she would be moving up and down with her  
21 hands to pump something.

22 Q. Okay. Did you talk with her any more  
23 specifically than the fact that she had been working  
24 with a bicycle pump at the time?

Robert Shull, M.D.

Page 29

1 A. No.

2 Q. All right. But was it your impression based  
3 on what she told you that she recalls the onset of the  
4 pain based upon that activity that she was engaged in in  
5 using the bicycle pump; is that right?

6 A. She at least -- she mentioned that.

7 Q. Okay.

8 A. It's not uncommon sometimes for people to date  
9 an important medical activity to something.

10 Q. Absolutely. And then she also told you it was  
11 approximately three to six months before she saw  
12 Dr. Norton in 2010 that she began to develop the  
13 complaints of pulling and ripping and that stabbing  
14 pain?

15 A. Yes.

16 Q. Okay. Did you see in the records that she  
17 told Dr. Norton that it had been that way since the mesh  
18 surgery itself?

19 MR. CANNON: I'll just object. I think it  
20 mischaracterizes the record.

21 MS. VAN STEENBURGH: All right.

22 A. I think I would have to see that note.

23 Q. Okay.

24 A. I mean, I can't remember that right off the

Robert Shull, M.D.

Page 30

1 top of my head, but I'd be glad to look at the reference  
2 if you would like me to do that.

3 Q. We'll -- I'll bring those out in a bit. On  
4 Page 10, Doctor, it looks like you are indicating that  
5 at your examination there were no signs of any vaginal  
6 bleeding, correct?

7 A. That's accurate.

8 Q. And there was a reference to her having used  
9 estrogen intermittently following her surgery in 2008.  
10 Was that something that she reported to you or something  
11 you gathered from the records?

12 A. Well, it's -- it became clear in the interview  
13 I had with her that she had used estrogen part of the  
14 time. She also later developed breast cancer, and I  
15 think she stopped her estrogen temporarily at least  
16 during the time she had the diagnosis in early  
17 management of her breast cancer.

18 It isn't uncommon for me to see people who may  
19 be on any number of medical regimens where their  
20 persistence in taking something on a regular basis waxes  
21 and wanes.

22 Q. And my question merely was the extent to which  
23 you talked with her about what her estrogen history had  
24 been. Do you have any more detail other than she had

Robert Shull, M.D.

Page 31

1       used it intermittently following the surgery?

2           A.    Not in this note, I don't.  There are  
3       -- there's information in the various outpatient visits  
4       she had with Dr. Sharp, with I think Dr. Summers was the  
5       doctor treating her infections, so there are multiple  
6       comments in Drs. Norton, Sharp, and Summers' note  
7       regarding advice to use estrogen and whether she was  
8       currently using it or not.

9           Q.    Do you recall seeing in her records that from  
10       the time of her hysterectomy until approximately the  
11       time that she saw Dr. Norton, she was taking estrogen  
12       via injection?

13          A.    I don't have that documented.

14          Q.    Does that refresh your recollection at all, my  
15       asking that question?

16          A.    No.

17          Q.    Okay.  Do you recall seeing anything in the  
18       records that she was taken off of estrogen and -- by  
19       Dr. Norton?

20          A.    No.

21          Q.    The injectable?  Okay.

22          A.    Oh, the injectable?  No.  She may have  
23       transitioned to the topical estrogen.  I don't remember  
24       the exact comment about that, but that would be a

Robert Shull, M.D.

Page 32

1 logical thing to do in someone in whom you want to  
2 treat specifically the vaginal tissue is ask them to  
3 use topical estrogen.

4 Q. Do you recall seeing anything in Ms. Dimock's  
5 records regarding any withdrawal she was having from no  
6 longer taking estrogen via injection?

7 A. No.

8 Q. Okay. Now, in the next paragraph, she  
9 indicates to you that she has no sense of any tissue  
10 bulging outside the vagina, correct?

11 A. That's accurate.

12 Q. And when you report that she says that she  
13 feels as if she is imploding on the inside of the  
14 vaginal canal, can you be any more specific as to how  
15 she was describing her feeling there --

16 A. Well --

17 Q. -- or is that -- are those just words that she  
18 used and you wrote them down?

19 A. Those are her words, which I would take to  
20 mean that's not a normal feeling and is not a pleasant  
21 feeling, and then she subsequently described pain. So I  
22 don't normally have patients use that particular word.  
23 I didn't ask her to expand on it --

24 Q. All right.



Robert Shull, M.D.

Page 33

1 A. -- any more than she did.

2 Q. And when she said that she describes pain as  
3 to her seat bones, do you know what she was referring to  
4 when she said "her seat bones"?

5 A. Oh, I think she means when she was sitting  
6 down, probably on what she wouldn't know would either be  
7 her ischial tuberosities or the lower part of her sacrum  
8 or coccyx, but in fact in that area there are also  
9 muscles and other tissues which would be related to  
10 sitting and hurting.

11 Q. The next paragraph describes a little bit  
12 about her issues with incontinence, correct?

13 A. Yes.

14 Q. And this is what she reported to you, that  
15 Dr. Norton had asked her to reduce her fluid intake  
16 because there might be a connection between her urge  
17 incontinence and the amount of fluid she was taking in?

18 A. Yes.

19 Q. All right. And, again, if you drop down a  
20 couple of paragraphs, she describes the pain in her seat  
21 bones and in the back part of the vagina, correct?

22 A. Yes.

23 Q. Was it your understanding that this is a  
24 constant pain that she experiences?

Robert Shull, M.D.

Page 34

1           A.    I believe she had told me. My later -- the  
2           last sentence in that paragraph said that there has not  
3           been a day or a week or a month where she's been  
4           pain-free since her surgery in 2008. That would lead me  
5           to think that she has pain on a regular basis, and it  
6           varies in intensity on a scale of zero to 10 between a  
7           four and a seven, and depending on what level it is, she  
8           may use aspirin or ibuprofen. Sometimes she would use  
9           Percocet, which has a synthetic codeine in it.

10          Q.    So as far as you can tell, this is a constant  
11          pain as opposed to an intermittent pain that she  
12          experiences?

13          A.    I think she has a constant level of pain and  
14          intermittently it changes.

15          Q.    Okay. In terms of the --

16          A.    She has a baseline pain component with  
17          intermittent changes in the intensity of the pain.

18          Q.    All right. And her report is that she's had  
19          that constant or baseline pain since the surgery in  
20          2008; is that right?

21          A.    Yes.

22          Q.    All right. Now, with respect to the  
23          examination that you performed, you note that external  
24          genitalia, Bartholin, Skene's, and urethra area are

Robert Shull, M.D.

Page 35

1       remarkable in that she has puncture sites from her prior  
2       trocar placement of the mesh products, correct?

3             A.    Yes.

4             Q.    Did you notice anything -- she had a procedure  
5       involving the Bartholin gland. Were you aware of that?

6             A.    Yes.

7             Q.    All right. And is one of the puncture sites  
8       related to that procedure, or are you saying that  
9       they're all related to use of the pelvic mesh product?

10            A.    It would be highly unlikely they would have  
11       been related to Bartholin's gland, unless someone made  
12       an incision in an unusual area.

13                   In order to deploy the mesh arms, there's a  
14       need to have puncture sites on the outside of the vulva,  
15       in what's called the perianal area. Those puncture sites  
16       sometimes heal where frankly it's quite difficult to see  
17       where the puncture was, and sometimes it's easier to see  
18       that. That could vary depending on wound healing or  
19       individual characteristics of a patient. It could in  
20       the case of early after surgery, it could be a  
21       reflection of infection in the wound site.

22                   The areas that I saw and commented on, I  
23       didn't see any acute signs of infection, and I couldn't  
24       expel anything from these puncture sites. They simply

Robert Shull, M.D.

Page 36

1       were there.

2               Q.    Okay.  And with respect to any of your  
3       opinions regarding Ms. Dimock's injuries, are you going  
4       to provide an opinion that her injuries were due in any  
5       part to the use and placement of a trocar for insertion  
6       of the device in this case?

7               A.    Yes.

8               Q.    And what's your opinion?

9               A.    About the trocar use, you mean?

10              Q.    Yes.

11              A.    Trocars, in order to be used in the case of  
12       a transvaginally placed mesh, have to traverse a number  
13       of tissue planes, depending on whether the trocar goes  
14       outside to inside or inside to outside, but the trocars  
15       traverse the skin; the external skin; the underlying  
16       fatty tissue, what's called fascia; muscles; the  
17       connective tissue of the vagina; and the skin of the  
18       vagina.  So in one way or the other, the trocars  
19       traverse all of those tissue layers and those tissue  
20       layers contain vessels, nerves, and areas where  
21       lymphatic drainage, for example, which you cannot see by  
22       simply looking at the skin any more than you could look  
23       at my hand and see everything underneath.  It just  
24       doesn't work that way.

Robert Shull, M.D.

Page 37

1                   So the trocars are passed in an area where  
2                   presumably it's safe in terms of not injuring a major  
3                   artery, a major vein, or a major nerve, but when the  
4                   trocars are introduced, the mesh arms then are deployed.  
5                   In general, the trocars themselves have a smaller  
6                   diameter than the width of the synthetic product. So  
7                   the trocar creates a passageway and when the arms are  
8                   deployed, the arms are not going to look the same as  
9                   they do when they come out of the package, for example;  
10                  and depending on where the trocars traverse, it's  
11                  entirely possible that there are going to be small  
12                  nerves, small vessels, possibly larger nerves or vessels  
13                  that could be injured because the trocars are passed not  
14                  under direct visualization but by palpation. That's the  
15                  nature of using them for anything, so it's not possible  
16                  to see everything.

17                  So in the case of the Prolift, which requires  
18                  multiple trocar passages, every time one is passed,  
19                  there is an opportunity for something to happen that you  
20                  wouldn't have anticipated, or every time an arm is  
21                  deployed, there is an opportunity for that arm of the  
22                  mesh product to lie adjacent to a nerve, a sensory  
23                  nerve, a muscle nerve. And then because of the  
24                  placement of these arms, the configuration invariably is

Robert Shull, M.D.

Page 38

1 going to be different than it is when the arm is simply  
2 lying out and hasn't passed through any tissue. So the  
3 trocars in this particular circumstance are important,  
4 because she required multiple trocar passages in order  
5 to deploy the arms in the mesh.

6 Q. Well, let me ask you a question, because I  
7 heard a couple of things there. One, is it your opinion  
8 that the trocar -- the trocar is used with respect to  
9 the Prolift product itself, the trocars themselves  
10 injured Ms. Dimock? Because I heard you say something  
11 about the trocars, but also when the mesh arms were  
12 deployed, that the placement of the arms could lie  
13 adjacent to a nerve, so I wanted to make sure I  
14 understood the difference between the two of those.

15 A. In the case of an immediate injury from the  
16 trocar itself, what we would expect to see is the mesh  
17 is deployed into the rectum, the bladder, or the  
18 urethra. There is no evidence that the trocars actually  
19 passed into the rectum or into the bladder or into the  
20 urethra, so that would be one possibility, where the  
21 trocar itself could have created an injury. There is  
22 nothing to suggest that. The trocars could penetrate a  
23 large blood vessel and there could be hemorrhage  
24 associated with the trocar placement. There is nothing

Robert Shull, M.D.

Page 39

1 in the record to indicate that there was an immediate  
2 hemorrhage.

3 The trocars could be placed so that instead of  
4 the mesh being deployed under the vaginal skin, the mesh  
5 could be deployed through the vaginal skin, and there is  
6 no evidence in the record to suggest that happened. The  
7 trocars do pass through innervated tissue with blood  
8 vessels in it in order to create a path to bring the arm  
9 back out. So in the sense that the trocars are  
10 important, they create the pathway for the arms to be  
11 deployed, and could they injure small nerves, small  
12 vessels, impede the -- by direct trauma? The answer is  
13 yes, they could.

14 So let's presume that there isn't any mesh  
15 product, but you simply took a group of women and took a  
16 trocar as big as basically a pencil and stuck it six  
17 times into the vaginal canal and out through the outside  
18 of the pelvis, could someone be injured from that, and  
19 the answer is yes.

20 In her case, she didn't have the trocar go  
21 through the bladder, urethra, or rectum. She didn't  
22 have excessive bleeding, but she in fact could have had  
23 trauma to those other structures, which could cause her  
24 to have pain. In that case, would the pain be chronic

Robert Shull, M.D.

Page 40

1 or would it be self-limiting? In all likelihood in the  
2 absence of actually severing a larger nerve, which could  
3 happen, but there is no evidence that happened here,  
4 trauma from the trocar passage itself is more likely to  
5 have a self-limiting period where there is bruising,  
6 swelling, and tenderness, but the trocar then brings the  
7 mesh product into that same pathway, and the product is  
8 there forever. So the issue, then, is could you get the  
9 product there without the trocar, and you can't. That's  
10 why they are trocar-based.

11 Q. So the question I had was -- I think the  
12 answer is no, if I hear you -- that there was not any  
13 immediate injury by virtue of using the trocar itself,  
14 correct?

15 A. There is no evidence of that.

16 Q. No evidence of that. And that's a possibility,  
17 but there is no evidence in this case, correct?

18 A. There is no evidence.

19 Q. All right.

20 A. We would see that if someone saw the trocar in  
21 the bladder, felt it in the rectum --

22 Q. Right.

23 A. -- saw it in the urethra, saw it in the  
24 vaginal tissue. I'm talking about through the vaginal



Robert Shull, M.D.

Page 41

1 skin. If we saw that, you could say, "Yes. The trocar  
2 was in the wrong place and it did something it  
3 shouldn't have done."

4 Q. And your opinion here is that the mesh itself  
5 was the cause of the pain and other injuries that  
6 Ms. Dimock suffered, not the trocars themselves,  
7 correct?

8 A. The trocar in and of itself isn't. The  
9 trocar -- the mesh couldn't have been deployed without  
10 the trocar.

11 Q. Understood.

12 A. So however you separate that out.

13 Q. Okay. Is it possible during a native tissue  
14 repair for there to be some kind of damage to any of the  
15 nerves or tissue?

16 A. Yes, it is.

17 Q. Okay. With respect to your pelvic exam, I  
18 note that the vaginal canal measures approximately seven  
19 centimeters deep.

20 A. Yes.

21 Q. Is that within a normal range based upon your  
22 experience?

23 A. It is. You know, everything is an average,  
24 just sort of whether you're tall or short or heavy or

Robert Shull, M.D.

Page 42

1 thin. There is an average somewhere. Not everybody is  
2 on the average. So seven centimeters for vaginal depth  
3 would probably be on the lower end of normal as opposed  
4 to a woman who has a vaginal depth that's 10 or 11  
5 centimeters, for example; but it still would fall within  
6 a range that's considered normal.

7 Q. And the reason I ask that is there are some  
8 references in the record to different measurements for  
9 Ms. Dimock's vaginal canal. Do you remember seeing  
10 those in the record?

11 A. Yes, I did.

12 Q. And they range some place between three  
13 centimeters and 10 centimeters, if I recall correctly?

14 A. Well, different parts are being measured.  
15 There is a system for measurement of specific areas of  
16 the pelvis. The acronym is POPQ, but the term is pelvic  
17 organ prolapse quantification. That system was created  
18 and published in 1966 -- 1996. I was on the committee  
19 who helped to design this objective way to measure  
20 things in the vaginal canal.

21 So we measure what's called the anterior  
22 compartment, the posterior compartment, the depth of the  
23 vagina, the vaginal opening, the perineal body. There  
24 are a variety of things that can be measured and

Robert Shull, M.D.

Page 43

1       documented in a grid form. Several of her reports from  
2       Dr. Norton have that grid; others simply indicate the  
3       depth of the vaginal canal.

4           Q.    And your measurement here was the depth of the  
5       vaginal canal; is that right?

6           A.    Yes.

7           Q.    All right. Now, are you going to give an  
8       opinion in this case that Ms. Dimock's vaginal canal was  
9       foreshortened by virtue of the fact that she had the  
10      Prolift device?

11          A.    I don't think I said that anywhere.

12          Q.    I don't think you did either. I just wanted  
13      to make sure.

14          A.    No.

15          Q.    The answer is no?

16          A.    No, I'm not going to do that.

17          Q.    All right. When you did the pelvic  
18      examination, you noticed that she had atrophy. What is  
19      atrophy?

20          A.    Atrophy in the vaginal canal is tissue that  
21      has reduced or no estrogen stimulation.

22          Q.    And what does that do to the tissue? Does it  
23      make it thinner --

24          A.    In general --

Robert Shull, M.D.

Page 44

1 Q. -- if there's no estrogen? I'm sorry.

2 A. In general, women who have atrophy of the  
3 vaginal canal may have the tissue be thinner, less  
4 lubricated, and if you were to be able to do a  
5 microscopic examination, there is reduced blood supply  
6 to the tissue in the vaginal canal.

7 Q. Okay.

8 A. The tissue then becomes less soft or  
9 distensible.

10 Q. Less elastic?

11 A. That could be a term.

12 Q. Okay. Then you say she has greatly increased  
13 pelvic floor muscle tone. What does that mean?

14 A. That means in general when a woman has a  
15 pelvic exam, if you ask her, she can relax the muscles  
16 that -- in the vaginal canal, what are called the  
17 levator muscles. Many woman can relax that on request.  
18 People who have chronic pain frequently cannot do that  
19 because they anticipate something is going to hurt, and  
20 human nature is to withdraw, and withdrawal usually  
21 means contraction of the muscles.

22 Q. And you note that initially you could only do  
23 a digital exam using your index finger, but it sounds  
24 like later on she was able to relax her muscles, and

Robert Shull, M.D.

Page 45

1       you were able to do a two fingerbreadth exam?

2           A.    I did.  And then I took the speculum, which I  
3       use.  Instead of using the top and the bottom of the  
4       speculum, I was able to use the bottom part only, so I  
5       could retract the area between the rectum and the vagina  
6       and look at the top part of the vaginal canal, the area  
7       under the bladder.  Then I could turn that around and  
8       look at the area between the rectum and the vagina.  So  
9       she allowed me to do that, but it was only after those  
10      muscles relaxed some.

11          Q.    Okay.

12          A.    That's not -- that would happen with people  
13      that have pain.  They have increased muscle tone.

14          Q.    Well, and people who have a certain amount of  
15      anxiety about examinations may tighten their muscles; is  
16      that --

17          A.    They may.

18          Q.    -- true?

19          A.    They may.

20          Q.    All right.

21          A.    And maybe because it hurts them.  They may be  
22      anxious because it hurts.

23          Q.    Well, when she was able to relax the muscles,  
24      you did an examination, and where did you find

Robert Shull, M.D.

Page 46

1       tenderness, if at all?

2           A.     There were several things I found on exam.  
3       One, on the anterior part of the vaginal canal, by the  
4       urethra and bladder, I could feel a small area that had  
5       a different consistency. My note indicates it was about  
6       four centimeters inside the vaginal opening. There was  
7       a well-defined area that could be scar tissue, could be  
8       a foreign body. By touch, it was not necessary -- you  
9       couldn't possibly tell for sure which one it is, but I  
10      described it as about the size of a small bean, and she  
11      was tender in that area.

12           Q.     So when you palpated that, was it something  
13      that moved under your touch, or was it a fixed feeling?

14           A.     It had minimal movement.

15           Q.     Okay.

16           A.     And then she was more tender, actually, to  
17      palpation on the opposite side of the vaginal canal near  
18      the top of the vagina on her left side.

19           Q.     Okay.

20           A.     And on that side, I didn't feel this, whatever  
21      that was, whether it was scarring or foreign body or  
22      induration. I didn't feel that on the left side, but  
23      she was tender.

24           Q.     And as we sit here today, you don't know what

Robert Shull, M.D.

Page 47

1 the small, bean-sized object consists of, correct?

2 A. That's accurate.

3 Q. All right. Are you going to speculate as to  
4 what you think it might be?

5 A. Well, I could tell you it's likely one of  
6 several things. It could be scar tissue. It could be a  
7 small piece of mesh that's there.

8 Q. Okay.

9 A. It could be something we didn't anticipate  
10 that is not scar tissue or not a piece of a foreign  
11 body, but that's not a likely thing to happen. There is  
12 no way to know it until it's actually excised and  
13 someone looks at it.

14 Q. I was going to say -- right. As you sit here  
15 today, you don't know, correct?

16 A. That's accurate.

17 Q. All right. And then on the rectal exam you  
18 say you noted some banding of tissue near the ischial  
19 spines on both sides.

20 A. Yes.

21 Q. When you say "banding," what do you mean?

22 A. That means normally when someone has a pelvic  
23 exam, including a rectal exam, there isn't any  
24 definitive three-dimensional structure that feels the

Robert Shull, M.D.

Page 48

1 same as -- for example, I'll give you my hand as an  
2 example, So -- and my finger, index finger and thumb  
3 are like this. This tissue is very soft. If I do that,  
4 that feels entirely different. That would -- to me,  
5 that would feel like a band.

6 So in examining her on rectal examination,  
7 what I felt near these landmarks, all the ischial  
8 spines, are these areas that were tighter and more tense  
9 and usually you don't feel that.

10 Q. Okay.

11 A. So that's not what you would find on most  
12 people's exam. That could be scarring. That could be a  
13 foreign body. It would be most likely one of those two  
14 things.

15 Q. And your examination, you did not find any  
16 erosion of the mesh, correct?

17 A. That's accurate.

18 MS. VAN STEENBURGH: All right. Can we go off  
19 the record for a second?

20 THE VIDEOGRAPHER: Going of the record. The  
21 time is 10:51.

22 (Recess was taken from 10:51 a.m. until 10:57 a.m.)

23 THE VIDEOGRAPHER: Back on the record. The  
24 time is 10:57.



Robert Shull, M.D.

Page 49

1 BY MS. VAN STEENBURGH:

2 Q. Doctor, I'd like to make sure that we are on  
3 the same page with respect to Ms. Dimock. What were the  
4 procedures that Dr. Housel or Housel performed in 2008  
5 relative to Ms. Dimock?

6 A. Ms. Dimock had previously had a hysterectomy.  
7 When he saw her for evaluation, he identified cystocele,  
8 rectocele, urinary incontinence. The procedures he did  
9 basically were placement of the anterior and posterior  
10 Prolift and placement of a transobturator tension-free  
11 vaginal tape.

12 His note details several procedures, including  
13 cystocele repair, rectocele repair, enterocele repair,  
14 and sacrospinous ligament suspension, and paravaginal  
15 repair. My interpretation of the note would be that he  
16 identified the cystocele, rectocele, enterocele,  
17 paravaginal defect, and the repair of those was  
18 accomplished using the anterior and posterior Prolift.  
19 In addition to that, he did the transobturator  
20 tension-free tape and performed cystoscopy.

21 Q. So is it your interpretation of his operative  
22 note that he did not do a sacrospinous ligament  
23 suspension?

24 A. I do not -- let me just read that note one

Robert Shull, M.D.

Page 50

1 more time.

2 Q. Sure.

3 A. I do not see in the operative note that he  
4 specifically exposed the sacrospinous ligament and  
5 placed any sutures in that ligament to secure the  
6 top of the vaginal canal or the graft, either one  
7 really.

8 Q. And so the absence of a description in his  
9 operative note is what leads you to believe he did not  
10 perform the sacrospinous ligament suspension?

11 A. It would lead me to believe he didn't document  
12 it if he did it.

13 Q. So it's possible he did perform it but did --  
14 his documentation is less than perfect?

15 A. Well, I don't know that.

16 Q. Well, I don't know that either, but I'm --  
17 we're trying to get to the bottom of what he really did  
18 do here.

19 A. He didn't include a description of the  
20 dissection to do a sacrospinous ligament fixation. Now,  
21 whether he did it or not is a different issue.

22 Q. All right. And he refers to -- there's a  
23 reference to a anterior and posterior colporrhaphy.  
24 That was -- that can be done with a native tissue

Robert Shull, M.D.

Page 51

1 repair, correct?

2 A. Yes, it can.

3 Q. All right. And in this case, it's your  
4 understanding in interpreting his operative note that he  
5 used the Prolift device on the anterior and also on the  
6 posterior, correct?

7 A. That's accurate.

8 Q. All right. And when there is reference in his  
9 operative report to repair of the enterocele via vaginal  
10 approach, what do you understand that to entail?

11 A. What he describes, an enterocele or the  
12 enterocele was identified. An enterocele is a type of  
13 hernia. It normally occurs between the tissue that  
14 should support the top of the vaginal canal and the  
15 rectum.

16 He says he identified an enterocele, and he  
17 plicated that with zero Ethibond purse-string suture,  
18 which would imply that he saw a hernia sac with the  
19 peritoneal surface between him and the inside of the  
20 abdominal cavity, and what he choose to do was take a  
21 nonabsorbable suture and take a circular stitch around  
22 this hernia sack. When he tied the suture, it should  
23 have obliterated the sac. And the reason he used  
24 purse-string, it would be very similar to the strings or

Robert Shull, M.D.

Page 52

1 cords on a coin purse, for example, where someone would  
2 pull the ends of that and close the top of the purse.

3 So his enterocele repair was using that one suture to  
4 reduce the size of the peritoneal sac that he saw.

5 Q. And based upon your experience, are you aware  
6 as to whether Ethibond sutures ever erode to the  
7 surface?

8 A. They may.

9 Q. Okay.

10 A. I use them quite regularly, actually, so I am  
11 familiar with that. In general, what happens with an  
12 Ethibond suture or anything similar that is not  
13 absorbable, you would like it to be underneath any skin  
14 incision, ideally with another layer of tissue between  
15 the skin and it, so that the skin and the soft tissue  
16 heal and the stitch is under it.

17 Sometimes what will happen is people will  
18 still react to that and at some time in the future, that  
19 stitch may be obvious on physical exam that it has been  
20 exposed through the skin incision.

21 Q. And have you been able to eliminate the  
22 possible exposure of the Ethibond suture in connection  
23 with any of the procedures that Dr. Norton--strike that.

24 Have you been able to eliminate erosion of the

Robert Shull, M.D.

Page 53

1 Ethibond suture in the case of Ms. Dimock?

2 A. Well, it's a single stitch that he used.

3 There is no evidence in any of the descriptions that

4 someone saw a single suture and removed it. The

5 Ethibond usually will have some color to it. It could

6 be a -- it could be white. It could have a color to it,

7 but there is no description of a specific stitch being

8 removed, so I didn't consider that as the problem

9 because no one said they saw it, and it wouldn't have

10 been placed in the location where the different mesh

11 exposures were seen. So I think that's highly unlikely.

12 Q. But the best person to answer that question

13 would be Dr. Norton probably, yes?

14 A. Yes. Well, if you ask her personally. Her

15 notes don't reflect that, and she has thorough notes.

16 Q. Understood. Now, your opinions as I

17 understand them is that Ms. Dimock's acute and chronic

18 pelvic pain and acute and chronic vaginal pain are the

19 result of Prolift, correct?

20 A. Are you referring to a specific place in my

21 report now?

22 Q. Yeah. I'm looking at Page 12, and I want to

23 make sure I understand your opinion.

24 A. Okay.

Robert Shull, M.D.

Page 54

1           Q.    So I'm actually going to repeat that so that I  
2           split those two up.  Are you offering an opinion in this  
3           case that Ms. Dimock suffered an onset of acute pelvic  
4           pain as a result of the Prolift?

5           A.    Well, she -- in her history, which I obtained,  
6           she had no pre-existing history of chronic pelvic pain,  
7           fibromyalgia, or the other things we've reviewed.  In my  
8           history, she says that she began to develop pain  
9           complaints following her surgery.  Now, for something to  
10          be acute, she may have had an acute onset of some pain  
11          complaints, but acute implies that the pain or whatever  
12          other symptom or sign it is, if it's acute, it would  
13          occur, and then the implication is it would be resolved  
14          some way or the other.  So her issue really is chronic  
15          pain.

16          Q.    Okay.

17          A.    Even though she may have had acute pain to  
18          begin with, the issue is it evolved into a chronic  
19          concern, which has interfered with her quality of life.

20          Q.    All right.  So just to make sure I understand.  
21          Your opinion is that Ms. Dimock has experienced chronic  
22          pelvic pain, which was caused by the anterior and  
23          posterior Prolift; is that right?

24          A.    Yes.

Robert Shull, M.D.

Page 55

1           Q.   All right. And your opinion also is that she  
2   has experienced and suffered from chronic vaginal pain  
3   caused by the anterior and posterior Prolift?

4           A.   Well, when you say pelvic pain --

5           Q.   Well, you have pelvic and vaginal here.

6           A.   I understand.

7           Q.   Okay.

8           A.   Pelvic pain can be a variety of things. It  
9   can be muscle pain, for example, in the vaginal canal --  
10   or in the -- not in the -- muscles not in the vagina.  
11   It could be muscles in the pelvis, vaginal -- or it  
12   could be chronic bladder pain, for example, and there's  
13   a typical history for chronic bladder pain.

14                   It could be chronic bowel complaints. There's  
15   a history for chronic -- I don't mean she has the  
16   history. There are histories for chronic bladder pain.  
17   There are histories for chronic bowel pain, which are  
18   different than her complaints.

19                   Then vaginal pain, most women would describe  
20   vaginal pain as a sensation that they may have either  
21   with having something placed in the vaginal canal, like  
22   a speculum or a tampon or a sex toy, or to have sexual  
23   intercourse, so vaginal pain usually implies something  
24   inside the vaginal canal, and pelvic pain is more likely

Robert Shull, M.D.

Page 56

1 to be considered in the nerves, the connective tissue,  
2 the muscles of the pelvis. And even though she may  
3 describe her complaints as shooting pain in the vagina,  
4 I don't doubt that she has them, so that could be  
5 classified as vaginal pain or pelvic pain, either one.

6 Q. All right. So I just want to make sure that I  
7 was understanding what your opinions are. So one  
8 opinion that you are going to offer in this case is that  
9 she, Ms. Dimock, suffers from chronic pelvic pain caused  
10 by the anterior and posterior Prolift, correct?

11 A. Yes.

12 Q. All right. Are you also going to offer an  
13 opinion that she suffers from chronic vaginal pain  
14 caused by the anterior and posterior Prolift based on  
15 your definition of vaginal pain?

16 A. Yes.

17 Q. All right. You are also going to offer an  
18 opinion that she experienced repeated episodes of mesh  
19 exposure that were caused by the anterior and posterior  
20 Prolift, correct?

21 A. Yes.

22 Q. All right. So let me ask you a couple of  
23 questions and let's start with erosion. Ms. Dimock  
24 underwent surgical procedures to remove eroded mesh on



Robert Shull, M.D.

Page 57

1 more than one occasion, correct?

2 A. That's correct.

3 Q. And if my notes are correct, she underwent  
4 that in four instances?

5 A. Yes.

6 Q. And as far as you know, there have been no  
7 other instances where she has undergone any kind of  
8 excision or surgical procedure for erosion of the mesh  
9 since 2014, correct?

10 A. She did not describe it to me, and I didn't  
11 see anything in her records to indicate that.

12 Q. All right. In some of the procedures where  
13 she underwent excision of the mesh, also involved lysing  
14 adhesions or releasing the mesh arms, correct?

15 A. That's accurate.

16 Q. All right. Now, with respect to erosion, is  
17 it your opinion that every erosion of mesh constitutes a  
18 serious complication?

19 A. In our literature there is an ongoing  
20 discussion about the proper term to use to describe,  
21 Is it mesh exposure? Is it something eroded or not? So  
22 in the case of mesh exposure, what may happen, as I  
23 understand it, is the patient herself may see or feel  
24 the mesh outside the vaginal incision in the canal, or

Robert Shull, M.D.

Page 58

1 the doctor may see it, and then they respond to topical  
2 estrogen treatment. They may respond to observation.  
3 It may respond to excising a small amount of mesh in the  
4 examination room in the office, for example.

5 Erosion, in my mind, usually means something  
6 that occurs at a later time away from the index surgery,  
7 frequently involves bleeding, spotting, discharge, could  
8 involve pain for the sexual partner, for example, and it  
9 could involve pain for the patient.

10 Erosions possibly could respond to topical  
11 estrogen. Depending on the surface area of the erosion  
12 and a variety of other things, that may be a reasonable  
13 thing to offer a patient. And then if they respond well  
14 to that, that may be the end of it, but in the case  
15 where that doesn't, the patient doesn't respond, then  
16 excision of the mesh is the only other therapeutic  
17 option.

18 Some doctors advocate removing only the part  
19 of the mesh that's visible and closing the skin edges  
20 over it. There are a few surgeons who recommend  
21 attempting to remove all of the mesh, which has been  
22 implanted. Most surgeons feel that trying to remove all  
23 of the mesh, particularly when mesh arms have been  
24 deployed, has a potential to create its own set of

Robert Shull, M.D.

Page 59

1 complications.

2 Q. And, Doctor, I appreciate that. I think we're  
3 getting a little off topic, and I only have a limited  
4 amount of time, so the question was whether you consider  
5 the mesh exposure here for Ms. Dimock as you've  
6 described in your report as a serious complication?

7 A. Well, it's serious enough that when we report  
8 on complications following surgery, a complication  
9 requires -- something with an operative intervention is  
10 a high-level complication.

11 There are scales for complications, the Dindo  
12 scale, for example. So some things require observation,  
13 some require medicine, some require something, but  
14 surgery, surgery moves up the scale of the significance  
15 of a complication.

16 Q. Right.

17 A. Because it requires an anesthetic, a recovery,  
18 and the whole works.

19 Q. All right. So in your mind, a serious  
20 complication involving exposure would be one that  
21 requires surgical intervention, as opposed to topical  
22 treatment with estrogen, for example, correct?

23 A. That's accurate.

24 Q. Or what about someone who the mesh exposure is

Robert Shull, M.D.

Page 60

1 trimmed in an in-office procedure, would that be a  
2 serious complication?

3 A. That would fall on the lower level of  
4 significance.

5 Q. Okay. Now, with respect to your opinion here,  
6 how is it -- in summary form, without going into long  
7 detail, you say the Prolift itself caused the exposure.  
8 Can you tell me what the basis of that opinion is?

9 A. Yes.

10 Q. And what is that?

11 A. She has a foreign body implanted in the vagina  
12 that has a significant surface area. The product itself  
13 and the package has a significant surface area.

14 In the case of Mrs. Dimock, she had an inter-  
15 val after her surgery that could have been 18 months or  
16 20 months where the mesh was not exposed, and then her  
17 complaints with pain increased. She had evidence of  
18 the exposure, and what I think most likely happened is  
19 the mesh product itself became shorter, either through  
20 scar contracture or contracture of the mesh product,  
21 and as it became shorter, there are fixed arms of  
22 the mesh that have gone through the muscles, nerves,  
23 and tissue in the vaginal canal, and those arms rarely  
24 move in terms of becoming looser. So the arms became

Robert Shull, M.D.

Page 61

1 tighter in much the way this becomes tight, and when the  
2 arms became tight, the central portion also became  
3 taught, interfered with blood supply to the skin, erodes  
4 through the skin, and then the skin is not able to heal  
5 over that. And the treatment and surgery for skin  
6 drainage, skin erosion, infection, and there is a  
7 foreign body, the treatment is to remove the foreign  
8 body, and in this case, the Prolift is the foreign body.

9 Q. Right. And we're talking about erosion, so as  
10 I understand your -- the basis for your opinion is that  
11 the Prolift product, either through scar tissue or  
12 because of the product itself, becomes more taught,  
13 closer to the surface, and then eventually the mesh then  
14 goes through the skin surface and is exposed; is that  
15 what I heard you say?

16 A. Yes, you did.

17 Q. All right. So did you take into consideration  
18 at all the -- this patient's characteristics in your  
19 opinion that it was the Prolift that caused the erosion?

20 A. Do you have a specific question about the  
21 patient characteristics?

22 Q. Sure. She's a smoker, right?

23 A. Yes.

24 Q. And she's been a smoker for 40 years, correct?

Robert Shull, M.D.

Page 62

1 A. Yes.

2 Q. What does smoking do to tissue?

3 A. Smoking affects estrogen metabolism. So the  
4 way smoking affects tissue in the vaginal canal is when  
5 women, primarily, make estrogen and it's metabolized in  
6 the body and they don't smoke, the estrogen metabolize  
7 to something that may have a significant amount of  
8 biological activity.

9 Smoking changes the metabolic pathway so that  
10 the estrogen metabolism pathway then results in an  
11 estrogen that is less biologically active. So if you  
12 see someone, for example, a woman, particularly who is a  
13 chronic smoker, frequently her skin will show that, the  
14 skin in her face. But the skin in the vaginal canal  
15 will more likely have reduced blood supply and be thin  
16 and dry.

17 Q. And so could her vaginal tissue be a  
18 contributing factor to the mesh erosion in her case?

19 A. It's possible.

20 Q. All right. How about the fact that Ms. Dimock  
21 engaged in self-examinations of her vaginal canal? Did  
22 you see that in the medical records?

23 A. I did.

24 Q. Could self-examination have contributed to any

Robert Shull, M.D.

Page 63

1 mesh erosion?

2 A. I think that would be extremely unlikely. It  
3 would be less likely, for example, in a woman who is  
4 having intravaginal intercourse or a woman who wears a  
5 tampon or a woman who has a speculum exam, so I think  
6 that would be a highly unlikely scenario unless you're  
7 dealing with someone who does self-mutilation. There is  
8 no evidence she does that.

9 Q. The erosion is a potential adverse consequence  
10 of using mesh, is it not?

11 A. Yes, it is.

12 Q. And that's something that Ethicon warned about  
13 it its IFU?

14 A. In the most general terms, not in very  
15 specific terms.

16 Q. Well, it did identify that as a potential  
17 consequence that might result in further surgical  
18 procedures, did it not?

19 MR. CANNON: I'll just object; argumentative.

20 A. Without quantifying when and how many times.

21 Q. And did you read Dr. Housel's deposition?

22 A. I did.

23 Q. And he was aware that erosion was a potential  
24 consequence, correct?

Robert Shull, M.D.

Page 64

1           A.    I think everyone knows superficially that it's  
2           possible.  What people -- including, I would say, the  
3           majority of doctors and probably all patients.  They  
4           don't understand that that event could occur at any time  
5           in the future and may or may not require multiple  
6           interventions to resolve.

7           Q.    And when you say that, have you done a study  
8           that forms the basis of that opinion?

9           A.    No.  I've read literature that would form the  
10          basis.

11          Q.    Okay.  And what literature are you relying on  
12          for that?

13          A.    The literature -- well, part of it comes from  
14          the University of Utah, for example, in evaluating women  
15          who were referred for mesh exposure and mesh  
16          complications, and on average, women required at least  
17          two and frequently more procedures to resolve the  
18          current issue.  And the potential concern about that is  
19          you don't know in the future how many of those people  
20          are going to come back again, so that's a snapshot in  
21          time.

22                        There's a report from the Cleveland Clinic,  
23          Mayo Clinic, University of Michigan, so there are  
24          multiple reports on the requirement for requiring more



Robert Shull, M.D.

Page 65

1       than one intervention to resolve these issues.

2           Q.    And intervention, are you referring to  
3       specifically a surgical intervention --

4           A.    Yes.

5           Q.    -- as opposed to an in-office procedure or  
6       topical treatment?

7           A.    It could be any or all of those, but  
8       specifically surgery.

9           Q.    All right.

10          A.    But it could include other things also.

11          Q.    Doctor, with respect to your opinion regarding  
12       the chronic pelvic pain that you -- that Ms. Dimock  
13       claims to experience, your opinion is that the chronic  
14       pelvic pain was caused by the Prolift, correct?

15          A.    Yes.

16          Q.    All right. And what is the cause of that  
17       pain? What is the mechanism as you understand it?

18          A.    Okay. In her particular circumstance, what I  
19       believe transpired with her, she had the product placed.  
20       I've already indicated to you the trocar passage in and  
21       of itself is a traumatic event. Surgery is traumatic.  
22       So trocar passage is traumatic, and she may have had  
23       some of her earlier complaints related to multiple  
24       trocar passages with an expectation that's reasonable

Robert Shull, M.D.

Page 66

1       that that's going to improve.

2               The fact is she acquired a set of complaints  
3       which haven't improved, despite several different  
4       attempts at therapy. And I believe the pathophysiology  
5       of what's happened is the mesh was put in place, may  
6       have been placed with relatively little tension, for  
7       example, and may not have bothered her for 18 months,  
8       particularly. I mean, it may have had some low level  
9       concern, but didn't come to her attention.

10              But as time goes on, the mesh contracts.  
11       There's degradation of the mesh. There's a chronic  
12       inflammatory response. There are nerves that grow into  
13       the mesh product. Those nerves can be sensory nerves,  
14       carrying pain, and they -- the product goes through  
15       muscle. It goes through the skin of the -- through the  
16       skin outside the pelvis and it goes underneath the  
17       vaginal skin, so there are any number of places where  
18       nerves could be entrapped and chronically irritated.

19              Q.   Well, let me ask you this: Doctor, is the  
20       cause of the pain, you know, as you say nerves are  
21       entrapped, you said the mesh contracts, is it the mesh  
22       that contracts, or is it the tissue around the mesh that  
23       contracts?

24              A.   Well, there is evidence to show the mesh

Robert Shull, M.D.

Page 67

1       itself contracts. There is literature to demonstrate  
2       that, but it could be a combination of scar tissue and  
3       mesh. But the fact is it's highly unlikely to see  
4       someone who doesn't have mesh products put in place to  
5       have these ongoing chronic pain problems that require  
6       multiple surgical interventions. That's a --

7           Q.    Well, let me ask you this. You attribute all  
8       of her chronic pelvic pain issues to the Prolift  
9       product, correct?

10          A.    I think that's likely, yes.

11          Q.    Okay. Did you -- when you were considering  
12       whether it was due to the Prolift product, did you take  
13       into consideration other procedures she had had?

14          A.    Such as?

15          Q.    The hysterectomy.

16          A.    I did, but there is no reason to think that  
17       would be related to her current complaints.

18          Q.    Well, I mean, you said any surgery is  
19       traumatic, and there could be a development of scar  
20       tissue relative to a hysterectomy; is that true?

21          A.    Not the complaints she has.

22          Q.    Okay. How about the -- you're aware that she  
23       had a wedge resection in 1972, correct?

24          A.    Of her ovaries?

Robert Shull, M.D.

Page 68

1 Q. Yes.

2 A. Yes.

3 Q. And, in fact, those procedures were  
4 discontinued because of the high rate of adhesions  
5 that occurred afterwards; is that right?

6 A. Related to fertility, not pain.

7 Q. Well, as a matter of fact, Ms. Dimock here,  
8 did she not make complaints about ovarian pain in her  
9 pelvis as part of the procedure when she was seeing  
10 Dr. Norton?

11 A. She may have said it seems similar to ovarian  
12 pain.

13 Q. And so can you eliminate the fact that there  
14 may have been some adhesional -- adhesions relative to  
15 the wedge resection, and that was causing some of the  
16 pelvic pain?

17 A. Well, the only way to be certain that someone  
18 has adhesions in the abdomen at all, whether they have  
19 pain or not, the only way to be certain of that is to  
20 look surgically, and no one looked in her abdomen  
21 surgically to see.

22 Q. Right. And I'm just trying -- I mean, you  
23 have come to the conclusion that all of her chronic  
24 pelvic pain is due to the fact that she had the Prolift

Robert Shull, M.D.

Page 69

1 device and I wanted to understand whether you considered  
2 other alternatives?

3 A. Oh, yes, I did. But let's just use that  
4 specific example. So 40 years ago she had wedge  
5 resection of her ovaries and didn't have the current  
6 complaints she has now. In 2008, she had the Prolift  
7 implanted and she's acquired these complaints. So just  
8 thinking about it logically, why would she have had a  
9 surgery 40 years ago that didn't bother her until she  
10 had the Prolift put in?

11 Q. And so she had an additional surgical  
12 procedure that could, in fact, have affected the  
13 adhesions from the wedge resection possibly? Yes?

14 A. That would be highly unlikely because the  
15 surgery that she had done in 2008 did not involve  
16 entering the abdominal cavity.

17 In Dr. Housel's note where you asked me about  
18 the enterocele, he specifically didn't enter the  
19 abdominal cavity, so if she had adhesions following the  
20 wedge resection, which it's possible she had them,  
21 they're inside the abdomen. That would be similar in  
22 this case to the four of us who are in this room and  
23 there is somebody out there. So could she have  
24 adhesions out there, but we're talking about everybody

Robert Shull, M.D.

Page 70

1 in here? That's conceivable, but that's not a logical  
2 conclusion to draw.

3 Q. Are you making a distinction between the  
4 pelvis and the abdomen in terms of your --

5 A. In terms of --

6 Q. You said the adhesions relative to the wedge  
7 resection would appear in her abdomen --

8 A. Yes.

9 Q. -- as opposed to her pelvis?

10 A. That's correct.

11 Q. Okay.

12 A. Through the abdominal cavity.

13 Q. All right.

14 A. No. That is correct. It would be what is  
15 called "intraperitoneal."

16 Q. All right.

17 A. Now, does the peritoneal cavity go down into  
18 the pelvis? It does, but those adhesions would be in-  
19 side the peritoneal cavity, and none of the procedures  
20 she had done entered the peritoneal cavity, so it would  
21 be -- I guess anything is possible -- that would be so  
22 unlikely that there'd be something inside her abdomen  
23 which is exaggerated by what was done here, unless a  
24 trocar was passed inadvertently into her abdomen and

Robert Shull, M.D.

Page 71

1 injured her bowel. Could that happen? It could, and  
2 if that were to happen, the patient would be sick.

3 Q. All right. You didn't see evidence of that  
4 here?

5 A. No. She didn't --

6 Q. Let me --

7 A. She didn't report any of it. She would have  
8 been sick, sick, sick if that happened.

9 Q. Let me ask you this just very briefly.

10 A. Uh-huh.

11 Q. She underwent a wedge resection, correct?

12 A. That's -- yes.

13 Q. And a hysterectomy, correct?

14 A. Yes.

15 Q. And an appendectomy, correct?

16 A. Yes.

17 Q. And she's also complained of pelvic plain  
18 issues related to GI issues, correct?

19 A. Right.

20 Q. And she's been diagnosed with diverticulitis?

21 A. In 2013.

22 Q. Okay.

23 A. Not in 2008 or '09 or '10.

24 Q. Well, and she's previously had abdominal pain

Robert Shull, M.D.

Page 72

1 for which she has undergone examination and treatment in  
2 the past, prior to 2008, correct?

3 A. She has, that's accurate.

4 Q. Yes. A left lower quadrant pain, some right  
5 lower quadrant pain; is that right?

6 A. That's accurate.

7 Q. All right. And Dr. Housel's procedure, was  
8 there any potential by virtue of the fact that he  
9 engaged in surgery that there may have been a potential  
10 for scarring?

11 A. From the pelvic reconstructive surgery, you  
12 mean, in the vaginal canal?

13 Q. Other than the Prolift, he also performed --  
14 it's a little questionable in your mind as to whether he  
15 performed the ligament suspension, correct?

16 A. Yes.

17 Q. All right.

18 A. And in general, if someone does sacrospinous  
19 ligament suspension, in general, that is done on either  
20 the left or the right side. Since his note doesn't  
21 describe what he did anyway, we don't know if he did  
22 left side, right side, or both sides, so --

23 Q. But can you eliminate that procedure as a  
24 possible source of any pelvic pain she might have?



Robert Shull, M.D.

Page 73

1           A.     Well, the natural history of pain following  
2     sacrospinous ligament suspension is when that operation  
3     is performed in America, it normally is performed on the  
4     patient's right side usually. It could be the left, but  
5     usually the right, and of the women who have  
6     sacrospinous ligament suspension, what may happen is in  
7     the early recovery and for the first eight or 10 weeks  
8     after surgery, maybe one out of 10 or one out of eight  
9     patients may say they hurt some on the side of the  
10    suspension.

11                The natural history is that pain goes away.  
12    So there aren't any syndromes described that I'm  
13    familiar with that says a person who has sacrospinous  
14    ligament suspension and then 18 months, 24 months, some  
15    time in the future, they acquire these unremitting pain  
16    complaints.

17           Q.    Can you eliminate that, then, as a source of  
18    her pain complaints?

19           A.    I wouldn't have considered it as the source of  
20    chronic pain complaints, and I don't think anyone who is  
21    knowledgeable about the procedure would.

22           Q.    How about the plication procedure that he  
23    engaged in with respect to the enterocele?

24           A.    I think that --

Robert Shull, M.D.

Page 74

1 Q. Can you eliminate that as a possible source of  
2 pelvic pain?

3 A. That is so highly unlikely it would like being  
4 hit by lightning.

5 Q. Can you eliminate it as a possibility?

6 A. I would.

7 Q. Okay. Can you eliminate any patient  
8 characteristics involving Ms. Dimock as a factor in her  
9 chronic pain?

10 MR. CANNON: I'll just object; ambiguous.

11 A. Specifically?

12 Q. Sure. Dr. Norton refers to Ms. Dimock's  
13 patient characteristics specifically about the fact that  
14 she has unusual scarring. Do you remember seeing that?

15 A. Uh-huh.

16 Q. And do you agree with Dr. Norton's statement  
17 in the medical records that some patients are not as  
18 suited as others for use of the Prolift device?

19 A. I think that's probably true. It may be no  
20 one is suited for it. How's that?

21 Q. Well, she also said that some people have  
22 successfully undergone surgery using the device and  
23 others have not. Do you agree with that?

24 A. I --

Robert Shull, M.D.

Page 75

1 MR. CANNON: Well, I just -- if we've  
2 got the record, I think that's the best thing to  
3 look at.

4 MS. VAN STEENBURGH: Sure.

5 A. Do I agree that some people have had the  
6 procedure and they haven't presented with complaints? I  
7 feel sure that's the case.

8 Q. Okay.

9 A. Now, what I don't know is what's going to  
10 happen to those women in the future, and no one knows  
11 the answer to that.

12 Q. Well, that's true with surgery as well with  
13 using native tissue, is it not?

14 A. It's much less likely true, because we have  
15 a hundred-year history of native tissue, 150 since  
16 anesthesia, and we have a -- in this particular case, we  
17 have a 10-year history, so they aren't the same.

18 Q. Doctor, would you agree with me that Ethicon  
19 warned about adhesion formation and contracture in its  
20 IFU?

21 A. I understand from reading the IFU that in very  
22 general terms there was a laundry list of things that  
23 were listed.

24 Q. The question was --

Robert Shull, M.D.

Page 76

1 A. Yes.

2 Q. Yes. Okay. Thank you. So let me make sure  
3 that I understand the basis for your opinion with  
4 respect to her pelvic pain. Doctor, it's your opinion  
5 that her chronic pelvic pain, which she claims to  
6 currently experience, is the result of a combination of  
7 the contraction of the mesh and contraction of scar  
8 tissue; is that right?

9 A. I'm sure they're associated with one other.

10 Q. Okay.

11 A. That the mesh incites inflammation, incites  
12 scar tissue, the mesh contracts, the wound contracts,  
13 nerves are irritated, the vascular supply is modified.  
14 They're all -- yes, they all go together.

15 Q. Okay.

16 A. Incited by having a foreign body in the  
17 pelvis.

18 Q. Well, as a matter of fact, any time you put a  
19 foreign body into a human, there is some kind of foreign  
20 body reaction, is there not?

21 A. There could be. This one happens to be one  
22 with a great surface area and then placed in a  
23 contaminated part of your body, which flies in the face  
24 of all surgical principles.

Robert Shull, M.D.

Page 77

1           Q.    Doctor, in your -- and you may be asked this  
2           in a more general way, are you relying on some  
3           particular literature that -- for the opinion that  
4           there's a greater chance of inflammation and chronic  
5           inflammation by virtue of the fact that this is placed  
6           in the contaminated area of the body?

7           A.    Yes.

8           Q.    Okay. And what's that literature?

9           A.    Well, it's all -- it's the history of medicine  
10          and surgery that placing a foreign body in a  
11          contaminated field is poor surgical judgment.

12                Now, do we do that sometimes? When we operate  
13          through the vaginal canal, yes, because the vaginal  
14          canal is never sterile. So when we operate through the  
15          vaginal canal and we use whatever procedures we use,  
16          suture material, let's say, we're putting it into a  
17          contaminated field. What happens, then, part of the  
18          time and in many cases, the suture material dissolves,  
19          so in a period of, let's say, 90 days or less, for all  
20          practical purposes, that suture material has been  
21          metabolized and is gone.

22                Sometimes -- and I do this -- I may use  
23          nonabsorbable sutures, pieces of suture, to accomplish  
24          part of the surgery, and occasionally some of those

Robert Shull, M.D.

Page 78

1 sutures will be exposed in the vaginal canal, and I can  
2 see them and I can remove them in the office or I may  
3 treat someone to estrogen hormone.

4 The thing that is different here is there is a  
5 significant surface area of material that is not only  
6 placed in the vaginal canal, but by virtue of using the  
7 trocars, that same material is brought out through  
8 multiple tissue layers in the bony and muscular pelvis.  
9 So the product, then, is exposed to all of this  
10 contamination in the vagina, in the muscles of the  
11 pelvis, it just is. That's what happens.

12 Q. Well, Doctor, is there a difference between  
13 infection and inflammation?

14 A. Inflammation --

15 Q. Is there a difference?

16 A. Yeah, there could be, yes.

17 Q. Okay. And are you talking with contamination  
18 and bacteria, are you talking about infection or  
19 inflammation?

20 A. Well, I'm talking about both actually  
21 because --

22 Q. Do we have any evidence here that Ms. Dimock  
23 suffered from a chronic infection as a result of having  
24 the Prolift?

Robert Shull, M.D.

Page 79

1           A.    Well, you -- in the path reports are the  
2           foreign-body giant cells, so you see chronic  
3           inflammation which leads to pain, for example.

4           Q.    Let me ask you the question, though.  Is there  
5           any evidence of any kind of chronic infection with  
6           Ms. Dimock that you've been able to identify?

7           A.    Well, let me look at the path reports.  I'm  
8           going to see exactly what they said.  I'll read what the  
9           pathologist said.  Did she have -- to answer your  
10          question:  Did she have an abscess in the pelvis?  Did  
11          she require hospitalization for treatment of high  
12          temperature elevated white blood count?  No, she didn't.

13          Q.    So you indicate that the path reports show --

14          A.    No.  I'm going to read the path report here.

15          Q.    I'm sorry.

16          A.    If I find it.

17          Q.    I thought you were answering my question about  
18          infection.

19          A.    Well, I am.  I just wanted to find the path  
20          report and see what the pathologist said.

21          Q.    Okay.

22          A.    Okay.  This is from February 2010.  The  
23          pathologist says, "Foreign material with adherent  
24          benign squamous mucosa exhibiting chronic inflammation

Robert Shull, M.D.

Page 80

1 and foreign-body giant cell reaction."

2 Q. That doesn't mean infection, correct?

3 A. It means inflammation.

4 Q. Right. And inflammation, with any foreign  
5 body, you would expect some of that reaction, would you  
6 not?

7 A. Yes.

8 Q. Okay.

9 A. And that would be why you would take the  
10 foreign body out. So if you stuck a splinter in your  
11 finger, you wouldn't leave it there.

12 Q. So if I had a heart valve and there is  
13 inflammation around the heart valve, you'd take it out?

14 A. That's different. But the answer may be yes,  
15 but the difference is the heart valve is placed in a  
16 noncontaminated area of the body. These meshes are  
17 placed in a contaminated part of the body.

18 Q. And contamination, in your definition, that's  
19 bacterial contamination, correct?

20 A. In the vaginal canal, yes.

21 Q. All right. That's all.

22 A. The path report from October 2010, chronic  
23 inflammation.

24 Q. Again, no sign of infection, correct?



Robert Shull, M.D.

Page 81

1           A.    Not on those two. I will see if I can find  
2           the rest of them. The path report from 2014, the  
3           pathologist did not see mesh on that one. I think we  
4           knew that -- you knew that already.

5           Q.    Right.

6           A.    And then there is one other path report that I  
7           don't have in front of me so -- but I have those three,  
8           two showed chronic inflammation and one showed just scar  
9           tissue.

10          Q.    And none of them showed any kind of infection,  
11          correct?

12          A.    Not acute infection.

13          Q.    All right. Doctor, do you remember seeing a  
14          reference in the medical records to the fact that  
15          Ms. Dimock was noticing -- let me see if I can get it  
16          correct -- staples in her pelvis?

17          A.    She may have described that.

18          Q.    And Dr. Norton talked to her about that,  
19          correct?

20          A.    Uh-huh. But there weren't any staples in her  
21          pelvis, not in her vagina. People use different terms  
22          to describe things, so patients by and large --

23          Q.    That's okay. You don't have to go on. I was  
24          just asking the question. There is a reference in the

Robert Shull, M.D.

Page 82

1 records to a permanent suture from the Bartholin gland  
2 repair, though, correct?

3 A. Right.

4 Q. All right. Doctor, are you claiming that pain  
5 Ms. Dimock expresses relative to her levator ani muscles  
6 is related to the Prolift device?

7 A. Yes.

8 Q. And how is it related?

9 A. Well, chronic inflammation, irritation incites  
10 a reaction in the tissues, and those trocars go through  
11 muscle. That's what they do. They go through levator  
12 muscles. That's what they're designed to do, and then  
13 they deploy mesh in there, and then the muscles heal the  
14 tract. The mesh gets smaller. It gets inflamed. The  
15 muscles contract. There are nerve fibers.

16 This isn't a giant leap to presume that if I  
17 stuck something as big as a pencil in you six times and  
18 put a product and pull it out six times that it's going  
19 to hurt somewhere.

20 Q. And so it's your opinion that any pain that  
21 she has experienced in her levator ani muscles is  
22 directly the result of having had the trocar passed  
23 through those muscles?

24 A. And deploy the mesh. It's both of those.

Robert Shull, M.D.

Page 83

1 It's not one or the other.

2 Q. And have you --

3 A. It's deploying that mesh through those  
4 muscles.

5 Q. Okay.

6 A. And the trocar is the way to do it.

7 Q. And have you eliminated Ms. -- Ms. Dimock  
8 underwent physical therapy for her levator ani muscles,  
9 correct?

10 A. Yes, she did.

11 Q. And in fact she improved, did she not?

12 A. Yes.

13 Q. All right. And have you eliminated her own  
14 anxiety and her -- well, as a possible reason for the  
15 muscle issues relating to her levator ani pain?

16 A. What I would -- my interpretation of that is  
17 that she acquired the complaints with pain and whatever  
18 anxiety, if any, she had before would have been  
19 exaggerated by virtue of the fact that it has now been  
20 almost eight years since she had surgery and six  
21 years since her first explant. So it's a reasonable  
22 thing to acquire complaints with anxiety if you hurt  
23 all the time. So do I think preexisting anxiety made  
24 her hurt? No. Do I think she's anxious? I probably

Robert Shull, M.D.

Page 84

1 would be too if I had six years of hurting.

2 Q. Well, in connection with your opinions in this  
3 case, did you take into consideration any of the  
4 personality characteristics of Ms. Dimock relative to  
5 anxiety or PTSD or any other psychological condition  
6 she's been diagnosed with?

7 A. I'm cognizant of it. PTSD has nothing in the  
8 to world to do with the exposed mesh that she has had  
9 removed. The operations --

10 Q. How about the anxiety and the pain?

11 A. Well, it may have something to do with being  
12 anxious. I don't doubt that. I mean, that's a disorder  
13 which I'm not personally familiar with, but it isn't  
14 shocking that someone with PTSD would be anxious.

15 Q. Did you take into consideration notes in her  
16 file relative to Ms. -- assessment of Ms. Dimock that  
17 she needs to be dramatic in order to focus?

18 A. I asked her about that.

19 Q. And what did she say? She denied it?

20 A. No. She didn't deny it. Some people are.

21 Q. Okay. And do you think --

22 A. Some people are dramatic.

23 Q. And do you think some people --

24 A. That doesn't mean that they're going to have

Robert Shull, M.D.

Page 85

1 mesh exposed in their vagina. Some people don't say  
2 anything.

3 Q. I'm not asking about mesh exposure. We're  
4 talking about the pelvic pain and the vaginal pain.

5 A. Right.

6 Q. Do you think that sometimes the issues with  
7 respect to anxiety or being dramatic may increase issues  
8 with respect to pain in any particular patient?

9 A. Is it possible? If she had no surgery, if she  
10 had no product implanted, and she walked in off the  
11 street and said that "I hurt," and I found nothing in  
12 her surgical history, nothing on physical exam, nothing  
13 in her medical history, and she said, "You know, I'm a  
14 pretty dramatic person and I need to do that to get  
15 attention," but nothing had ever happened to her before,  
16 then I would be thinking, well, maybe that's an  
17 attention-getting device. I don't think that in this  
18 woman. That's not the case with her.

19 She specifically had something done that  
20 required deployment of these products in her vagina and  
21 whether she had PTSD or any other thing is unrelated to  
22 putting a product in her, unless someone knows that  
23 people with PTSD shouldn't have these procedures done.

24 Q. Can those diagnoses in any way -- forget the

Robert Shull, M.D.

Page 86

1 product --

2 A. Uh-huh.

3 Q. Can they be in any way related to the  
4 complaints of pain?

5 A. I suspect without knowing it for a fact that  
6 if you or I had PTSD and we were responding to anything  
7 under the sun, a nightmare, a dream, a loud noise, it  
8 would be different than someone who doesn't have it.  
9 So I'm sure it affects how people respond to things.

10 Q. And, now, are you aware that Ms. -- Ms. Dimock  
11 told you she had not had sex since before the implant,  
12 correct?

13 A. For one year, before.

14 Q. Right. Did you ask her why there were  
15 notations in her medical records where she indicated  
16 that she was having dyspareunia?

17 A. No. I think that wouldn't be her  
18 responsibility. That would have been the person  
19 documenting the record's responsibility for entering  
20 that, because she was very clear to me and I suspect to  
21 everybody else that she didn't have a sexual partner.

22 Q. So Dr. Norton would be wrong if Dr. Norton  
23 noted that she was experiencing dyspareunia?

24 A. What the patient could have said --

Robert Shull, M.D.

Page 87

1 Q. Well, you know, the question is whether  
2 Dr. Norton was wrong.

3 A. Well, if you don't have --

4 MR. CANNON: I'll just object. I think we're  
5 getting argumentative.

6 A. Well, what I'll say is I don't know about  
7 Dr. Norton's being wrong. What I would say is  
8 dyspareunia is pain with intercourse.

9 Q. Okay. How about when Dr. Sharp, did you see  
10 the record where he said that Ms. Dimock reported to him  
11 that she was having pain with sexual intercourse?

12 A. Well --

13 Q. Would that have been an incorrect record as  
14 far as you know?

15 A. Well, what she told me was she hadn't had  
16 intercourse since the year before.

17 Q. Okay.

18 A. I wasn't there when she gave a history to  
19 Drs. Norton and Sharp, so God only knows what she  
20 told them.

21 Q. Did you ask her about whether -- I guess you  
22 did ask her, and she said she had not had intercourse,  
23 correct?

24 A. Yes.

Robert Shull, M.D.

Page 88

1 Q. All right.

2 A. And I didn't -- the time I saw her, I hadn't  
3 reviewed all of those records.

4 Q. Okay.

5 A. So that would have required me getting on the  
6 phone and saying, "You know, I saw you in November.  
7 When did you tell them?" I didn't -- she didn't give  
8 me that history.

9 Q. All right. So at the time that you examined  
10 her, you had not reviewed any records where there had  
11 been a report of dyspareunia; is that what you're  
12 saying?

13 A. That's accurate.

14 Q. All right. Ms. Dimock has had some issues  
15 with constipation and bowel movements, correct?

16 A. Yes.

17 Q. And did you eliminate those issues as a  
18 possible source of any pelvic pain in connection with  
19 your opinion that the pain she experiences is strictly  
20 related to the Prolift device?

21 A. Well, could she have pain with the  
22 constipation? She could. Would she have chronic pain  
23 with the physical findings that she has and the history  
24 she has and constipation be the primary cause of her



Robert Shull, M.D.

Page 89

1 complaint? And the answer is no.

2 Q. Now, Doctor, you are of the opinion that  
3 Ms. Dimock would not have experienced the issues she  
4 did, specifically mesh erosion and chronic pain, had she  
5 had a native tissue repair; is that correct?

6 A. Yes.

7 Q. All right. So with respect to mesh erosion,  
8 that's because in a native tissue repair, there is no  
9 mesh used, correct?

10 A. That's accurate.

11 Q. All right. Do you have an opinion as to  
12 whether -- are you going to express an opinion as to  
13 whether a native tissue repair in the case of Ms. Dimock  
14 would have been more effective?

15 A. The information that we have about native  
16 tissue repairs -- I'll use rectocele. So the information  
17 we have about native tissue repair for rectocele,  
18 depending on the patient's complaints in advance, the  
19 patient could have complaints of a bulge, they could  
20 have complaints of inability to empty the distal rectum,  
21 they could have complaints of discomfort with  
22 intercourse, or they could have no complaints, falls in  
23 those four categories.

24 With native tissue surgery, what we know is

Robert Shull, M.D.

Page 90

1       seven out of 10 women will have improvement in their  
2       bowel function, and nine out of 10 will have reduction  
3       of the bulge, not a hundred percent in either one. We  
4       know that. We know that some women may have  
5       postoperative pain complaints. It is highly unlikely  
6       they would be chronic.

7           Q.    Okay.

8           A.    What we know about mesh products and the  
9       posterior vaginal canal for rectocele, there are no  
10      reports that indicate improved outcomes in rectocele  
11      repair with mesh. None.

12          Q.    I understand that. The question I had is:  
13      Are you going to issue or render an opinion or testify  
14      at trial that, in fact, a native tissue repair in the  
15      case of Ms. Dimock would have been more effective than  
16      the use of mesh in this particular patient?

17          A.    Well, what do you mean by more effective?

18          Q.    That there would have been -- the chance of a  
19      recurrence would have been -- is higher and was higher,  
20      and that if she had had a native tissue repair, the  
21      chance of a recurrence would have been lower. Can you  
22      say that with any definitive --

23          A.    What I can say in her particular circumstance  
24      if she had a native tissue repair, she wouldn't have had

Robert Shull, M.D.

Page 91

1       these four extra surgeries.

2           Q.    I understand the four extra surgeries have to  
3       do with the mesh.

4           A.    Right.

5           Q.    Lysing the mesh arms and the erosion. But the  
6       question is efficacy. Would there have been a  
7       difference? And you can just say to me, "I'm not going  
8       to say that I have an opinion one way or the other as to  
9       whether a native tissue repair would have been more  
10      effective." I don't care. I just want to make sure I  
11      understand what you're going to say.

12          A.    What I'm going to say is there is no  
13      literature that documents that using a mesh product is  
14      better, is more effective. So if there is nothing to  
15      say that it's more effective, then what you're left is  
16      are they equal, or is one inferior to the other? So  
17      could a mesh product be equal in resolving the anatomic  
18      abnormality, the bulge?

19          Q.    Right.

20          A.    They could be equal. One is not better than  
21      the other.

22          Q.    All right.

23          A.    But the issue, if that's all you look at, then  
24      you could say the anatomic outcomes may be similar, but

Robert Shull, M.D.

Page 92

1       that isn't all we look at.

2           Q.    I understand that, but that was my question.

3       So now we'll get to the second question, which is your  
4       opinion is had she had a native tissue repair, being  
5       an anterior or posterior colporrhaphy --

6           A.    Right.

7           Q.    -- your opinion is that would have been a  
8       safer procedure, because there would be fewer  
9       complications, correct?

10          A.    That's accurate.

11          Q.    All right. Now, I want to make sure that I  
12       understand, though. With any surgery, with a native  
13       tissue repair, there is a chance or there is a  
14       possibility that there can be pelvic pain, correct?

15          A.    What I would say is perfect doesn't exist.

16          Q.    Right. There is no surgical procedure that's  
17       perfect; is that right?

18          A.    That's accurate.

19          Q.    All right. And with an anterior or posterior  
20       colporrhaphy, if there were existing adhesions from some  
21       other procedure, that wouldn't make a difference in  
22       terms of Ms. Dimock's outcome; is that right?

23          A.    Well, I'm going to be a little bit more  
24       specific. There could be findings in the vaginal canal,

Robert Shull, M.D.

Page 93

1 and that would be very specific to a woman who has had  
2 radiation therapy in the vagina. So for some diseases  
3 of the pelvis, cancer of the cervix or cancer of the  
4 lining of the uterus, some women are treated with  
5 radiation in the vagina causing scarring, and there  
6 could be problems with vaginal surgery associated with  
7 that.

8 When the adhesions are inside the abdomen,  
9 which would happen after abdominal hysterectomy or ovary  
10 surgery or whatnot, when adhesions are inside the  
11 abdomen and the surgery is done through the vaginal  
12 canal without entering the abdomen, there shouldn't be  
13 anything done vaginally that would be an  
14 intra-abdominal problem.

15 Q. And to go back -- strike that.

16 MR. CANNON: Let's go off the record for a  
17 second.

18 THE VIDEOGRAPHER: Going off the record. The  
19 time is 11:55.

20 (Recess was taken from 11:55 a.m. until 12:02 p.m.)

21 THE VIDEOGRAPHER: Back on the record. The  
22 time is 12:02.

23 BY MS. VAN STEENBURGH:

24 Q. Dr. Shull, a couple of follow-up questions.

Robert Shull, M.D.

Page 94

1 One, I believe that you testified that they're -- with  
2 respect to Ms. Dimock, either the mesh itself  
3 contracting or the scar tissue formed around the mesh  
4 contracting is a source of Ms. Dimock's chronic pelvic  
5 pain, correct?

6 A. That's accurate.

7 Q. All right. And have you looked at literature  
8 regarding scarring in connection with the Prolift  
9 device?

10 A. Yes, I have.

11 Q. Is there anything different reported in the  
12 literature than what you see here with respect to  
13 Ms. Dimock?

14 A. You mean on her clinical exam?

15 Q. Right. Either on the clinical exam when you  
16 did it or anything in her medical records that would  
17 indicate the scarring or adhesions in her particular  
18 case are different from what you have seen in the  
19 literature relative to the Prolift device?

20 A. My impression is her history is compatible  
21 with the chronology of what can happen with patients is  
22 that they can have an interval where they're relatively  
23 pain free followed by an interval of progressive chronic  
24 pain because of these changes in the mesh, the

Robert Shull, M.D.

Page 95

1 shrinkage, the contraction, the degradation, the chronic  
2 inflammation, so I think her history actually fits what  
3 some people are -- in fact do experience.

4 Q. How about the type of scarring here in this  
5 particular situation described by Dr. Norton, is that  
6 different or is that consistent with what you have seen  
7 reported in the literature as to scarring that occurs  
8 with a Prolift device?

9 A. It's similar to what I've read about and it's  
10 similar to what I have seen personally in revising mesh  
11 in patients who have required it.

12 Q. Is it different in some way? You say it's  
13 similar, but is there a difference in some way?

14 A. Well, I think every patient is different, so  
15 the surgical dissection by her description is tedious,  
16 difficult in developing tissue planes between the  
17 bladder, the bowel, the vaginal skin, difficulty in  
18 exposing the mesh through the scar, so those things are  
19 all --

20 Q. So does it sound like it's --

21 A. -- characteristics I've observed when I've  
22 done mesh explantation myself, and there are things that  
23 are described in the literature that the surgery is  
24 technically difficult to do. And that's exactly what

Robert Shull, M.D.

Page 96

1 Dr. Norton's note describes. She describes banding,  
2 bunching, tissue being taught, difficulty in developing  
3 tissue planes, so those are all various characteristics.

4 Q. There is a reference in Dr. Norton's notes to  
5 the scarring in this particular case with Ms. Dimock  
6 being unusual based upon Dr. Norton's experience. Did  
7 you note that?

8 A. Well, I think she probably means it's  
9 unusually tedious to take care of it is what she --

10 Q. Well, you don't know what she means, correct?

11 A. No. I would think she means it's unusually  
12 difficult to do.

13 Q. Well, in terms of if we are describing the  
14 adhesions themselves, would you agree or disagree that  
15 they are unusual based upon what is generally reported  
16 in the literature?

17 MR. CANNON: I'll object; speculation.

18 A. I don't think I can say that I know that.

19 Q. Okay. And when you say that it's consist with  
20 what you have experienced or what you've seen in the  
21 literature, you're talking about the difficulty of  
22 removing the mesh?

23 A. That's accurate. Identifying it, dissecting  
24 it out, and protecting the surrounding structures so you



Robert Shull, M.D.

Page 97

1 don't injure the bowel, the bladder, the urethra, the  
2 vaginal skin.

3 Q. Okay. Are you're not talking about the actual  
4 adhesion constitution itself; is that right?

5 A. That's correct.

6 MS. VAN STEENBURGH: Let's just go off the  
7 record for a second. I want to ask Doug something.

8 THE VIDEOGRAPHER: Going off the record. The  
9 time is 12:07.

10 (Recess was taken from 12:07 p.m. until 12:09 p.m.)

11 THE VIDEOGRAPHER: Back on the record. The  
12 time is 12:09.

13 BY MS. VAN STEENBURGH:

14 Q. Doctor, other than the opinions expressed in  
15 your expert witness report and those that you have  
16 described today, are there any other opinions that you  
17 intend to give at the trial of this matter of  
18 Ms. Dimock?

19 A. I'm not aware of it.

20 Q. All right. And have you been asked to  
21 supplement your report at all?

22 A. No.

23 MS. VAN STEENBURGH: Okay. And to the extent  
24 you do, we will ask for a further deposition on

Robert Shull, M.D.

Page 98

1           that. That's all I have. Thank you.

2           THE WITNESS: Thank you.

3           THE VIDEOGRAPHER: This concludes the  
4           deposition of Dr. Shull in the Dimock case. Going  
5           off the record. The time is 12:09.

6           (The digital recording ended at 12:09 p.m.)

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Robert Shull, M.D.

Page 99

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CERTIFICATE OF REPORTER

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I, Danielle C. Coleman, Stenographic Shorthand Reporter, do hereby certify that I was authorized to and did transcribe the foregoing proceedings from digital recording, and that the transcript, pages 1 through 98, is a true and correct record.

Dated this 15th day of March, 2016.

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Danielle C. Coleman

Stenographic Shorthand Reporter